

REMARKS

In view of the following remarks, the Office is respectfully requested to allow claims 11, 13-15, 27, 31, 39-44, the only claims pending and under examination in this application.

Claims 1-10, 12, 16-26, 28-30 and 32-38 stand previously cancelled without prejudice against their reintroduction into this or any other timely filed continuation, divisional or continuation-in-part applications.

By this Amendment, claims 43-44 are newly added, exemplary basis for which may be found in claims 13 and 14 as originally filed and throughout the Specification, such as, for example, at page 6, lines 11-25, as well as in the experimental data presented in a murine model beginning at page 18, line 14.

Exemplary support for the amendments to Claim 11, 41 and 42 may be found throughout the Specification, such as, for example, at page 8, lines 7-16. Exemplary support for the amendments to Claim 27 may be found throughout the Specification, such as, for example, at page 11, lines 11-24. All other amendments are for purposes of clarity, and to create proper antecedent basis. These amendments do not change the scope of the claims and have been made solely to place the claims in condition for allowance. Entry thereof by the Examiner is therefore respectfully requested.

Claim Rejections – 35 U.S.C. § 102

Claims 11, 13-15, 27, 31, and 39-42 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Fogarty et al. (U.S. Patent No. 6,291,243).

Because the hallmark of anticipation is prior invention, in order for a rejection of a claim under 35 U.S.C. §102 to be properly founded, an Examiner must establish that a single prior art reference not only discloses all elements of the claim within the four corners of the document, but that it also discloses those elements as they are “arranged in the claim.”¹ In *Net MoneyIn, Inc. v. Verisign, Inc.* 2008 U.S. App. LEXIS 21827 (Fed.

¹ *Net MoneyIn, Inc. v. Verisign, Inc.* 2008 U.S. App. LEXIS 21827 (Fed. Cir. Oct. 20, 2008) citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983). See also, e.g. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986), *cert denied*, 480 U.S. 947 (1987); *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003); and *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631 (Fed. Cir.

Cir., Oct. 20, 2008), the Federal Circuit clarified what a reference must show in order to anticipate a claimed invention. There, the invention at issue recited an Internet payment system comprising five “links.” The lower court, after finding all five links in a prior art reference, albeit in two separately disclosed examples, held the invention anticipated. The Federal Circuit reversed, reasoning that the prior art reference, which disclosed two separate protocols for processing an Internet credit card transaction, could not be anticipatory because neither of these protocols contained all five links arranged or combined in the same way as claimed. The Federal Circuit stated that a reference that discloses all of the claimed ingredients, but not in the order claimed, does not anticipate.² Specifically, “[t]he test is thus more accurately understood to mean ‘arranged or combined in the same way as in the claim.’”³

Anticipation cannot be found, therefore, unless a cited reference discloses all of the elements, features or limitations of the presently claimed invention, in the same order or arrangement as claimed.

Here, claim 11 is drawn to a method of inserting an exogenous nucleic acid into the genome of a mouse or rat, wherein an element of the claim is a P-element derived vector comprising “a single transcriptionally active gene” and a “pair of P-element transposase recognized insertion sequences” wherein the single transcriptionally active gene “is separated from one of said P-element transposase recognized insertion sequences by a distance of about 1,000 bp or less.” Independent claims 41 and 42 recite similar elements. With respect to the other dependent claims included in this rejection, they incorporate all limitations of independent claims 1 and 41-42 from which they depend. It follows that the claims under consideration all specify the above elements.

The Examiner points to col. 5, lines 5-10 of the ‘243 patent for support for the single transcriptionally active gene embodiment, and to col. 4, lines 6-7 for support for the element of the single transcriptionally active gene being “separated from one of said

1987).

² *Net MoneyIn, Inc.* at 22.

³ *Id.*

P-element transposase recognized insertion sequences by a distance of about 1,000 bp or less.”

Yet, col. 4, lines 6-7 of the ‘243 patent refers to the length of the “inter P feet domain,” not the distance between one P-element transposase recognized insertion sequence and the single transcriptionally active gene specified in the claims. The “inter P feet domain” is the domain or region of the vector located or positioned between both of the P feet which includes the “at least two transcriptionally active genes and the exogenous nucleic acid” referred to in the ‘243 patent (see col. 4, lines 1-11 of the ‘243 patent). This passage does not refer to the distance between one of the P-element transposase recognized insertion sequences and the single transcriptionally active gene, which as presently claimed must be 1,000 bp or less.

The two disclosures in the ‘243 patent that the Examiner attempts to combine to formulate a basis for an anticipation rejection cannot form such under 35 U.S.C. §102, and under the current interpretation of that law, because these disclosures occur in disparate parts of the document and do not describe elements that are “arranged or combined in the same way as claimed.”⁴

It is not enough that a prior art reference disclose part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.⁵ “[T]he [prior art] reference must clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.”⁶ Accordingly, withdrawal of the rejection under 35 U.S.C. § 102(e) is appropriate and respectfully requested.

⁴ *Net MoneyIn, Inc. v. Verisign, Inc.* 2008 U.S. App. LEXIS 21827 (Fed. Cir., Oct. 20, 2008) at p. 27

⁵ *Id.* at pp. 28-29.

⁶ *Id.* citing *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) (emphasis in original).

Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 11, 13-15, 27, 31 and 39-42 were rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification allegedly does not enable any person skilled in the art to make and use the claimed invention commensurate in scope with the claims.

At page 11 of the Office Action mailed April 25, 2008, however, the Office has indicated that subject matter such as that presented in amended independent claims 11 and 41-42 is enabled by the instant specification:

Therefore, in view of the lack of guidance provided by the specification as well as the unpredictability of the art, the claimed invention is not enabled for its full breadth and limiting the scope of the claimed invention to a method of inserting an exogenous nucleic acid into the genome of a mouse or a rat, wherein said method comprises introducing into said mouse a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is less than 1000 bp proximity to one of the P-element transposase recognized sequences and a transposase domain, and a method of inserting an exogenous nucleic acid into the genome of a mouse, wherein said method comprises introducing into said mouse a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is less than 1000 bp proximity to one of the P-element transposase recognized sequences, wherein said method further comprises inserting a second P-element vector comprising a transposase domain, and cells from said mouse or rat is proper.

It is Applicants' understanding that by the above passage, the Examiner has indicated that enablement is found in the following two situations:

(1) where the claims specify that the subject methods involve introducing a P-element derived vector into the genome of a mouse or rat or cells thereof, the vector comprising a transcriptionally active gene located within 1,000 bp of one of two P-element transposase recognized insertion sequences, the two P-element transposase recognized insertion sequences flanking the transcriptionally active gene and a

heterologous promoter, **AND** wherein the P-element derived vector also comprises a transposase domain; and

(2) where the claims specify that the subject methods involve introducing a P-element derived vector into the genome of a mouse or rat or cells thereof, the vector comprising a transcriptionally active gene located within 1,000 bp of one of two P-element transposase recognized insertion sequences, the two P-element transposase recognized insertion sequences flanking the transcriptionally active gene and a heterologous promoter, **AND** that the subject methods further involve introducing a second P-element derived vector comprising a transposase domain separately into the genome of the mouse or rat or cells thereof.

It is believed that the currently presented amendments to the independent claims reflect the Examiner's position in the above passage. Thus, based on the Examiner's comments at page 11 of the Office Action mailed April 25, 2008, and the amendments to claims 11 and 41-42 herein, allowance of these claims and their dependences is respectfully requested. Applicants respectfully request that the rejection under U.S.C. § 112, first paragraph, be withdrawn.

CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Office finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number TOSK-007CIPCON.

Respectfully submitted,
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